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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,617	08/12/2003	James E. Darnell JR.	600-1-073CIPCON	5404

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/639,617	DARNELL ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 36-38, drawn to receptor recognition factor (rrf)/ISGF3, classified in class 530, subclass 350.

II. Claims 8-13 and 39-42, drawn to antibodies to rrf and cell lines producing the antibodies, classified in class 435, subclass 240.26.

III. Claims 14-20, 43, 44 and 55, drawn to nucleic acids and transformants, classified in class 435, subclass 325.

IV. Claims 21-24 and 27, drawn to an assay for rrf using an rrf binding partner, classified in class 436, subclass 518.

V. Claim 25, drawn to an assay for rrf binding sites, classified in class 436, subclass 501.

VI. Claim 26, drawn to an assay for drugs that modify rrf activity, classified in class 436, subclass 63.

VII. Claims 28-30, drawn to a test kit, classified in class 436, subclass 808.

VIII. Claims 31-35, drawn to methods of treatment via administration of rrf, inducer, mimetic or inhibitor, classification dependent upon species.

IX. Claims 45-54, drawn to a method of enhancing interferon activity by either enhancing phosphorylation of ISGF-3 proteins or inhibiting the activity of a phosphatase enzyme, classified in class 514, subclass 12.

X. Claims 56-62, drawn to antisense nucleic acids, DNA encoding them and method of creating a cell line, classified in class 435, subclass 325.

XI. Claims 63-68, drawn to ribozymes, nucleic acids encoding them, a cell line and a method of making same, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

2. The protein of group I is related to the antibody of group II by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

3. The protein of group I is related to the nucleic acids of group III by virtue of the fact that the nucleic acids code for the protein. The nucleic acids have utility for the recombinant production of the protein in a host cell. Although the nucleic acids and the protein are related, since the nucleic acids encode the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, nucleic acids can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

4. The protein of group I is related to the method of using the specific binding partner of group IV by virtue of the fact that the protein is bound by the specific binding partner. The inventions are distinct, however because the protein is not used in the method of using the specific binding partner and is not necessary for that method. Therefore, the inventions are distinct.

5. Inventions I and (V, VI, VIII and IX) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used in the materially different processes V, VI, VIII and IX.

6. Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein of Group I and the binding partner of Group VII do not require each other for their practice; have separate utilities, such as use of the Group I proteins to screen compounds for inhibitory activity versus use of the Group VII binding partners to immobilize the proteins for analysis; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale

from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

7. Inventions I and (X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein of Group I and neither the antisense nucleic acids of Group X nor the ribozymes of Group XI require each other for their practice; have separate utilities, such as use of the Group I proteins to screen compounds for inhibitory activity versus use of the Group X antisense nucleic acids to hinder expression of nucleic acids and the Group XI ribozymes for catalyzing chemical reactions; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

8. The antibody of group II and the nucleic acids of group III are related by virtue of the protein that is encoded by the nucleic acids and necessary for the production of the antibody. However, the nucleic acids themselves are not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

9. Inventions II and (IV and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group II can be used in the materially different processes of Groups IV and V.

10. The antibody of group II is related to the method of testing the ability of a drug to modulate the activity of rrf of Group VI, the methods of treatment by administration of rrf of Group VIII and the method of enhancing interferon activity of Group IX by virtue of the fact that the antibody binds rrf. The inventions are distinct, however because the nucleic acids is not used in the method of treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

11. Inventions II and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because an antibody is only one example of a specific binding partner that could be used as part of the test kit. The subcombination has separate utility such as immobilization of rrf.

12. Inventions II and (X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group II and neither the antisense nucleic acids of Group X nor the ribozymes of Group XI require each other for their practice; have separate utilities, such as use of the Group II antibody to detect rrf versus use of the Group X antisense nucleic acids to hinder expression of nucleic acids and the Group XI ribozymes for catalyzing chemical reactions; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

13. The nucleic acids of group III are related to the methods of using the protein of groups IV, V, VI, VIII and IX by virtue of the fact that the protein is encoded by the nucleic acids. The inventions are distinct, however because the nucleic acids are not used in the method of treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

14. The nucleic acids of group III are related to the test kits of group VII by virtue of the fact that the protein is encoded by the nucleic acids. The inventions are distinct,

however because the nucleic acids are not used in the method of treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

15. The nucleic acids of group III are related to the antisense nucleic acid of group X by virtue of the fact that the nucleic acids are the opposite strand of the antisense nucleic acid. The nucleic acids molecules have utility for the recombinant production of the protein in a host cell. Although the nucleic acids and the antisense nucleic acid are related, since the nucleic acids are the opposite ("sense") strand, they are distinct inventions because the antisense nucleic acid has separate utility such as blocking expression of the protein encoded by the sense strand of the nucleic acids. Further, the sense strand of the nucleic acids can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

16. Inventions III and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Group III and the ribozymes of Group XI do not require each other for their practice; have separate utilities, such as use of the Group III nucleic acids to encode rrf versus use of the Group XI ribozymes for catalyzing chemical reactions; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have

acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

17. Inventions IV and (V, VI, VIII and IX) are patentably distinct from each other. The different methods do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

18. Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as an assay for rrf binding sites.

19. Inventions IV and (X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions clearly have no relationship to each other.

20. Inventions V and (VI, VIII and IX) are patentably distinct from each other. The different methods do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

21. Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as an assay for rrf.

22. Inventions V and (X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions clearly have no relationship to each other.

23. Inventions VI and (VIII and IX) are patentably distinct from each other. The different methods do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

24. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as an assay for rrf.

25. Inventions VI and (X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions clearly have no relationship to each other.

26. Inventions VII and (VIII, IX, X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions clearly have no relationship to each other.

27. Inventions VIII and (IX, X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions clearly have no relationship to each other.

28. Inventions IX and (X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions clearly have no relationship to each other.

29. Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions clearly have no relationship to each other.

30. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and searches, restriction for examination purposes as indicated is proper.

31. If Group VIII is elected; the following further election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: administration of rrf, administration of an agent capable of promoting the production of rrf, administration of an agent capable of promoting the activity of rrf, administration of an agent capable of mimicking the activity of rrf, administration of an agent capable of inhibiting the production of rrf and administration of specific binding partner of rrf.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 31-35 are generic.

32. If Group IX is elected; the following further election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: administration of a compound that enhances the phosphorylation of intracellular ISGF3 proteins and administration of a compound that inhibits the activity of a phosphatase enzyme.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 45-54 are generic.

With regard to paragraphs 31 and 32 above, Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

33. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

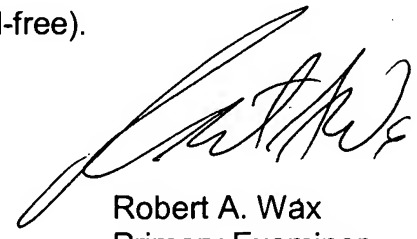
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax
Primary Examiner
Art Unit 1653

RAW